Inspection report on compliance with HTA licensing standards
Inspection date: **18 September 2024**

Princess Alexandra Hospital
HTA licensing number 12458

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Princess Alexandra Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Princess Alexandra Hospital ('the establishment') had met the majority of the HTA's standards, six major and five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	SOPs relating to body storage do not include processes to ensure all bodies in storage are shrouded. (See *shortfall* against standard PFE2(g)) *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The establishment does not routinely receive three points of identification from visitors when attending a viewing of a body. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	At the time of inspection freezer storage was at maximum capacity. Capacity for frozen storage has been reached twice in 2023. The establishment does not have sufficient freezer capacity.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have capacity for frozen storage of bariatric patients. There is an added risk as documented procedures do not include contingency plans if this storage was required. This shortfall was identified at a previous inspection however the establishment have not been able to find a mitigation.	**Major**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Fridge and freezer alarms are tested annually. The frequency of testing does not give assurance that units are functioning correctly or that the escalation process in event of an alarm event is effective.	**Major**
g) Bodies are shrouded or in body bags whilst in storage	At the time of inspection bodies were not consistently shrouded.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst there is an SOP for consent, it does not include what training a person seeking consent must receive.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Whilst refrigeration plant equipment is located within a gated compound, an area of incomplete fencing exists. As a result, access to the plant equipment is possible. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment did not have any alert devices in place for lone workers in the Mortuary. This inhibits the ability of lone working staff to call for assistance. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	Mortuary freezers have been utilised by the establishment to store anatomical waste awaiting disposal. The storage arrangements impact the dignity of the deceased. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
d) Fridge and freezer units are in good working condition and well maintained	Whilst fridge and freezer units are in good condition and are clean the seals on unit doors require decontamination.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	T1(d)	The DI is advised to review SOPs and ensure that reference is made to the same and similar name process. Furthermore, the DI may wish to consider alert systems in addition to the electronic register.
2.	PFE2(c)	The DI is advised to plan for the future provision of long-term storage of bariatric bodies.
3.	PFE2(f)	The DI is advised to ensure access to the settings of the refrigeration monitoring control panel is made available to users.
4.	PFE3(a)	The vacuum unit attached to the oscillating saw is showing early signs of corrosion. The DI is advised to monitor this.

5.	PFE3(c)	The DI is advised to follow up actions identified in the ventilation verification report of January 2024 to ensure air flows in the Mortuary continue to meet compliance.

Background
Princess Alexandra Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Princess Alexandra Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2022. Since the previous inspection the establishment have undertaken significant scoping work to identify facilities for freezer provision of bariatric bodies however it has been unable to resolve this issue.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection
All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The inspection team reviewed documentation on site and submitted after the inspection. Standard operating procedures, risk assessments and policies were reviewed. Audit schedules, competency records, cleaning record forms and meeting minutes were inspected as part of the review process.

Visual inspection
The inspection included a visual assessment of the body storage areas in the mortuary, PM room, viewing room and tissue storage areas. The inspection team observed the processes for release of bodies within the mortuary.

Audit of records
A traceability audit of five bodies in storage was undertaken. This included bodies from both the community and hospital including those with same and similar names and one in long term storage. Details were cross checked against identity bands and the mortuaries' electronic database. No discrepancies were found.

Audits were conducted of tissue taken at PM examination for three cases. Information was crosschecked between the mortuary electronic database, Coroner's paperwork, family wishes forms, the laboratory database, and tissue blocks and slides being stored. No discrepancies were found.

Meetings with establishment staff
The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Mortuary Manager, Bereavement Midwife and Porter.

Report sent to DI for factual accuracy: 11 October 2024

Report returned from DI: 25 October 2024

Final report issued: 29 October 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or

- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.